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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/773,826	01/31/2001	John D. Roback	050508-1030	7152

7590

02/10/2004

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EXAMINER
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CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/773,826	Applicant(s) ROBACK ET AL.	
	Examiner LaToya I. Cross	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 12-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 25-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>08/01</u> | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of claims 1-11 and 25-29 (group I) in the paper dated October 17, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### *Drawings*

2. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the washer (140) as described in the specification. In the specification, Applicants describe the washer in terms of its size, shape and function (specification page 7). However, in the drawings it appears that the reference character (140), which is described as the washer, points to the filter vessel system and not to a structural element having the size and shape to allow reagents to be washed from the filter vessel. Clarification is requested.

3. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1, 2-6, 8, 11 and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,620,898 to Yaremko et al.

Yaremko et al teach an automated blood analysis system. The system comprises a microcolumn (122), incubator (200), centrifuge (500), pipette assembly (400), washer (406, 410) and imaging system (606). The incubator holds containers/receptacles while reagents and fluids are being dispensed into the containers and incubates the containers, as recited in claims 1 and 25 (col. 5, lines 39-42). The containers/receptacles are microcolumns having a filter through which the assay sample travels. The filter is made of either beads or a porous gel material, as recited in claims 1, 3 and 4. The beads have a size of 10-100 microns, as recited in claim 5. See col. 6, lines 9-32. The centrifuge rotates the containers within it (containing the assay sample) to push the cellular material in the sample through the filter material and thus separate the sample, as recited in claims 1, 8, 25 and 27 (col. 13, line 61 – col. 15, line 3). The imaging system comprises a camera (644) for capturing an image of the analysis of the sample, as recited in claims 1 and 25 (col. 15, line 48 – col. 16, line 21). The pipette assembly comprises a pipette (402) and a robot arm (404), as recited in claim 1 (col. 13, lines 1-12). With respect to the washer recited in claim 2, Yaremko et al teach that washers (406, 410) contain liquids for rinsing or cleaning (col. 13, lines 23-28).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 10 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yaremko et al in view of US Patent 5,968,731 to Layne et al.

The disclosure of Yaremko et al is described above. Yaremko et al fail to teach a flow cytometer in the system for image acquisitioning.

Layne et al is directed to an apparatus for automated testing of biological specimens. Layne et al teach that image acquisitioning in automated analyses allows detection of target individual cells and allows the collection of data to be observed by the user later. Layne et al teach that flow cytometry is suitable for image acquisition (col. 14, lines 14-19; col. 17, lines 34-39). It would have been obvious to one of ordinary skill in the art to modify the Yaremko et al reference by substituting the camera imaging system for a flow cytometry imaging system, as taught by Layne et al. In testing of blood specimens, such a modification would allow the user to detect and analyze individual blood cells.

9. Claims 9 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yaremko et al in view of US Patent 5,603,899 to Franciskovich et al.

The disclosure of Yaremko et al is described above. Yaremko et al fail to teach a vacuum system for separating the sample.

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Franciskovich et al teach an apparatus for separating samples into their constituents. The reference teaches that both centrifuges and vacuums provide good means for separating multiple samples into their base constituents simultaneously. See col. 2, lines 25-31. Thus, it would have been obvious to substitute the centrifuge assembly of Yaremko et al with a vacuum assembly as disclosed by Franciskovich et al to allow simultaneous separation of multiple samples and thus increase the sample processing time.

10. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yaremko et al in view of US Patent 6,008,040 to Datar.

The disclosure of Yaremko et al is described above. Yaremko et al fail to teach the particular filter materials recited in claim 7.

Datar teaches efficient separation of cells, cellular materials and proteins. Specifically, Datar teaches separation devices such as bead columns. Further, Datar teaches that cellulose acetate beads, polyesters, and nylons are suitable for use in separation columns due to their specific chemistries on their contacting surfaces (col. 4, lines 24-41). It would have been obvious to one of ordinary skill in the art to use filter materials, such as cellulose acetates, polyesters, and nylons as the filter material in the microcolumn of Yaremko et al. These materials are known to be suitable in the separation of cellular material. The ordinarily-skilled artisan would have expected that these filter materials would perform sufficiently in separating blood cells.

*Double Patenting*

11. Claims 1-11 and 25-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 14 of copending Application No. 10/602,981. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of 09/773826 recite a system comprising a filter vessel, incubator, sample separation system, image acquisition system, and robotic pipettor. The independent claim of 10/602,981 recites only the vessel and has dependent claims which recite an incubator, sample separation system, image acquisition system and robotic pipettor. It would have been obvious to one of ordinary skill in the art to combine each of the structures (vessel, incubator, separation system, image acquisition system and pipettor) into one system to allow samples to be processed more efficiently since the sample need only be introduced into one system, as opposed to being introduced into five different devices for processing. One system which allows all the processes to be carried out automatically reduces the need for user interference and thus increases the efficiency of the processes.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Examiner.

LIC

January 24, 2004

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700